EXACTECH
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K010434

Exactech® Optetrak® B-Series Total Knee System

Summary of Safety & Effectiveness

MAR 1 3 2001

Sponsor: **Exactech® Inc.**
2320 N.W. 66th Court
Gainesville, Florida 32653

Phone: **(352) - 377 - 1140**
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FDA Establishment Number 1038671

Contact: **Gary J. Miller, Ph.D.**
V.P. of Research and Development

Date: **February 12, 2001**

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Summary of Safety & Effectiveness

Classifications / Proprietary Names:

Classification Name:	Prosthesis, knee, patellofemorotibial, semi-contrained, cemented, polymer/metal polymer
Trade / Proprietary Model Names:	Optetrak B-Series Total Knee System
Product Code:	JWH
C.F.R. Section:	888.3560
Device Class:	II
Classification Panel:	Orthopedic

Legally Marketed Devices for Substantial Equivalence Comparison:

The Optetrak B-Series femoral and modular tibial components are similar to the Exactech Optetrak Total Knee and devices marketed by other manufacturers:

Model	Manufacturer	510(k) Number
Cemented Total Knee System Tibial Components	Exactech, Inc.	#K933610
Posterior Stabilized Cemented Total Knee System	Exactech, Inc.	#K933494
Cruciate Retaining Cemented Tibial Component	Exactech, Inc.	#K932776
Zimmer	Insall/Burstein II	----------
Biomet	Maxim	----------
Johnson & Johnson	P.F.C. Sigma	----------

Exactech® Optetrak® B-Series Total Knee System

Summary of Safety & Effectiveness

Device Information:

INDICATIONS

The OPTETRAK® Total Knee Systems are indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

CAUTION: For cemented use only in the USA.

CONTRAINDICATIONS

The OPTETRAK® Total Knee Systems are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, patients without sufficient soft tissue integrity to provide adequate stability, and in patients with either mental or neuromuscular disorders that do not allow control of the knee joint, and in patients whose weight, age, or activity level might cause extreme loads and early failure of the system.

DEVICE DESCRIPTION

The Exactech Optetrak B-Series Total Knee System consists of femoral components and modular style tibial components. The components are compatible with Exactech's Optetrak line of patellar implants.

Optetrak B-Series femoral and tibial components are cast from Cobalt Chromium conforming to ASTM F-75. The tibial tray components are composed of UHMWPE conforming to ASTM 648.

Instrumentation is used to prepare the distal femur and proximal tibia. The Optetrak B-Series femoral is designed such that a close running fit is created between the distal femur and the box of the femoral component. Cement pockets are provided in the implants to enable the cement to be pressurized during the impaction of the implant onto the bone. Similarly, instruments are provided to create a close running fit in the proximal tibial for the stem on the tibial component. Optetrak B-Series components are intended for cemented applications only.

Exactech® Optetrak ™ B-Series Total Knee System

510(k) Summary of Safety and Effectiveness Special 510(k)

PACKAGING MATERIALS

Material	Composition
Inner / Outer Trays	PETG – 0.040" thickness
Tray Lids	Spun-Bonded Olefin - Tyvek®
Inserts	Medium grade LD45 Foam
Box	Heavy weight cardboard
Outer Shrink-Wrap	Clear, Light-Weight Plastic
Shipping Cartons	Heavy-weight Corrugated Cardboard

STERILIZATION INFORMATION

Method: Gamma radiation (Cobalt 60 source)
Dose: 25 – 37 kGy
Sterility Assurance Level (SAL): 10^{-6}

PERFORMANCE DATA

Functional testing and engineering analysis was conducted to verify that the implant performance would be adequate for anticipated *in vivo* loading. This data includes an evaluation of the modular tibial locking system, a tibial/femoral contact stress analysis, cyclic fatigue data, a fatigue strength evaluation and a determination of the intrinsic stability of the system. Results of the performance testing supports the conclusion that the Optetrak B-Series Total Knee System is substantially equivalent to other devices legally marketed in the United States, most notably Exactech's Optetrak Total Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2001

Ms. Lisa Simpson
Regulatory Representative
Exactech
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K010434
Trade Name: Optetrak® B-Series Total Knee System
Regulatory Class: II
Product Code: JWH
Dated: February 12, 2001
Received: February 13, 2001

Dear Ms. Simpson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Optetrak B-Series Total Knee System

Indications for Use

510(k) Number: K010434

Device Name: Optetrak B-Series Total Knee System

INDICATIONS
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for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010434

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes or Over the Counter Use No